510(k) Summary

General Provisions	Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned subsidiary of C.R. Bard, Inc.]
	Address:	605 N 5600 W Salt Lake City, UT 84116
	Telephone Number:	(801) 595-0700 ext. 5484
	Fax Number:	(801) 595-5425
	Contact Person:	Susan Scott
	Date of Preparation:	August 8, 2007
	Registration Number:	1720496 BAS 2212754 C. R. Bard
Subject Device	Trade Name:	Titanium PowerPort™ *isp* Implanted Port with 8 Fr. ChronoFlex® Polyurethane Catheter
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Predicate Devices	Trade Name:	Titanium PowerPort™ Implanted Port with 8 Fr. ChronoFlex® Polyurethane Catheter
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Premarket Notification:	K060812, clearance date July 14, 2006
	Trade Name:	MRI PowerPort™ Polymeric Implanted Port with 8 Fr. ChronoFlex® Polyurethane Catheter
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Premarket Notification:	K063377, clearance date Jan 25, 2007
Classification	Class II 21 CFR §880.5965 General Hospital	
Performance Standards	Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.	
Intended Use	PowerPort™ devices are totally implanted vascular access devices designed to provide long-term, repeated access to the vascular system.	

Indications for Use	The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.
Device Description	The subject Titanium PowerPort™ *isp* device is a member of the PowerPort™ series of power injectable implanted ports. The subject device consists of a titanium port and 8 Fr ChronoFlex® polyurethane catheter that is attached to the port with a cathlock (compression fitting). The subject Titanium PowerPort™ *isp* device is distinguishable as a member of Bard Access Systems's power injectable port series by the triangular body shape, unique purple coloring, and three palpation bumps on the septum. PowerPort™ implanted ports can be used for routine vascular access using a non-coring access needle. However, for power injection procedures, PowerPort™ ports must be accessed with a Bard PowerLoc™ safety infusion set to create a power injectable system.
Technological Characteristics	Technological characteristics of the subject Titanium PowerPort™ *isp* device with 8 Fr ChronoFlex® polyurethane catheter are equivalent to those of the Bard Access Systems predicate Titanium PowerPort™ device [K060812]. This equivalence extends to basic design, generic materials, construction, and surface anodization treatment. The distinguishing difference exists in the reduced size of the subject port body. The subject port catheter is unchanged from the predicate.
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, design verification testing was performed according to protocols based on the recommendations/requirements of applicable FDA guidance and FDA recognized international standards. Verification testing, determined to be applicable to the safety and efficacy of the device, was shown to meet predetermined acceptance criteria listed therein. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with an internal protocol based on ISO 14971:2000, *Medical Devices – Risk Management for Medical Devices*. The analysis did not identify any new types of safety or efficacy questions for the subject Ti PowerPort™ *isp* device with 8 Fr ChonoFlex® polyurethane catheter.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Ti PowerPort™ *isp* device with 8 Fr ChronoFlex® polyurethane catheter meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available power injectable implanted ports cited as predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2007

Ms. Susan D. Scott
Regulatory Affairs Specialist
C.R. Bard, Incorporated
Bard Access Systems
605 North 5600 West
Salt Lake City, Utah 84116

Re: K072215
Trade/Device Name: Titanium PowerPort™ isp Implanted Port with 8 Fr ChronoFlex® Polyurethane Catheter
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT, FPA
Dated: October 1, 2007
Received: October 2, 2007

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

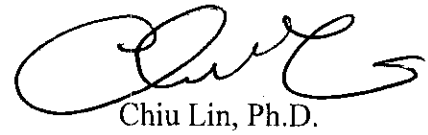
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Titanium PowerPort™ *isp* Implanted Port with 8 Fr ChronoFlex® Polyurethane Catheter

Indications for Use:

The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...Sign-Off)
...ion of Anesthesiology, General Hospital,
...Control, Dental Devices

...mber: K991215